

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Specification

Please replace the paragraph at page 2, lines 8-20 with the following paragraph.

Vaginal or rectal applicators for the delivery of a small volume of pharmaceutical preparation, i.e. ~~less than~~ 1 mL or less, are disclosed herein. The delivery of a small volume of a pharmaceutical preparation allows for the transvaginal delivery of the preparation to the region of the upper vaginal vault or rectum for the treatment of diseases and disorders of the female urogenital system, cervix, uterus, ovaries, fallopian tubes and peritoneal cavity and the lower abdomen. The vaginal or rectal applicators contain four main parts: an applicator barrel, a plunger, a plunger tip, and an applicator cap. The applicator functions similar to a syringe. The applicator is breech-filled with a pharmaceutical preparation with the plunger in the back position. The applicator cap is attached to seal the pharmaceutical preparation in the applicator. To use the applicator, the cap is removed, the applicator is positioned, and the plunger is depressed.

Please replace the paragraph bridging pages 3 and 4 with the following paragraph.

As shown in Figure 2A, the applicator barrel (15) is generally in the form of tube with an grip area (35) at its distal end, a flange (40) next to the grip area and an opening (45) at its rounded tip (33). Figures 2B and 2C show that the applicator barrel is a thin-walled tube. The cavity at the tip of the tube is the medication chamber (50). The diameter of the medication chamber (50) is smaller than the outer diameter of the applicator barrel. The medication

AMENDMENT AND RESPONSE TO OFFICE ACTION

chamber is large enough to contain a small volume of a pharmaceutical composition, which is less than 1 mL or less. In the preferred embodiment, the medication chamber is able to contain 200 μ L of a pharmaceutical composition. Next to the medication chamber is a barrier (55), which prevents the plunger from pushing beyond the medication chamber. After the plunger is depressed, the barrier locks the plunger in place. In one embodiment, length from the flange to the tip of the applicator barrel is greater than or equal to 4 inches. Thus when the vaginal or rectal applicator device is inserted in a patient, the tip of the applicator barrel is inserted more than four inches into the vaginal cavity or is approximately four inches into the vaginal cavity. For rectal administration the length may be less than or equal to four inches. Alternatively, for some embodiments, a shorter applicator, with a length ranging from 1 to 2 inches, is useful. For example, for rectal administration of a pharmaceutical composition to the anal canal, a length of 1.5 to 2 inches is useful. Additionally, for applicators that are used to administer pharmaceutical compositions to children an applicator with a shorter length, such as approximately 1 inch, is useful.

Please replace the paragraph at page 5, lines 14-23 with the following paragraph,

The applicator is breached filled, i.e. though the opening (45) at the tip (33) of the applicator barrel (15), with a pharmaceutical preparation with the plunger in the back position. A small volume of pharmaceutical preparation, *i.e.* less than 1 mL or less, is placed in the medication chamber. In a preferred embodiment, 0.2 mL of a pharmaceutical preparation is placed in the medication chamber. The pharmaceutical preparations may be in the form of a

AMENDMENT AND RESPONSE TO OFFICE ACTION

powder, gel, cream, lotion, suppository, ovule, tablet, or capsule. After filling the applicator, the applicator cap is attached to seal the pharmaceutical preparation in the applicator. To use the applicator, the cap is removed, the applicator is positioned in the patient's vagina or rectum, and the plunger is depressed.